

OCT 21 2005

K052294 v1

510(k) Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Shoulder Nail Plate	Plate Fixation Bone

Name of Predicate Devices

The **Shoulder Nail Plate** is substantially equivalent to the following predicate devices:

- Shoulder Fixation System, 510(k) No. K051728 – June 20, 2005 – Hand Innovations, LLC
- Dorsal Nail Plate of the Distal Radius Fracture Repair System, 510(k) No. K023007 – December 5, 2002 - Hand Innovations, LLC
- T2™ Proximal Humeral Nailing System, 510(k) No. K043404 – December 27, 2004 - Stryker Corporation.

Classification

Class II.

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

The **Shoulder Nail Plate** of the Shoulder Fixation System is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal Humerus.

Device Description

The bilaterally symmetric **Shoulder Nail Plate** is intended to treat fractures in both left and right Humerus. The plate segment of the **Shoulder Nail Plate** is intended to be attached to the metaphysis of the humerus. The nail segment of the **Shoulder Nail Plate** is intended to be inserted into the humeral diaphysis for optimal stabilization of the fracture.

Biocompatibility

The **Shoulder Nail Plate** do not require biocompatibility testing because the stainless steel used in fabrications meets the requirements of ASTM F 138-03.

Summary of Substantial Equivalence

The **Shoulder Nail Plate** is substantially equivalent to the predicate Shoulder Side Plate of the Shoulder Fixation System with regards to the intended use, materials, biocompatibility, and overall performance characteristics. The equivalence was confirmed through pre-clinical testing.



OCT 21 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ernesto Hernandez
Vice President, RA/QA
Hand Innovations, LLC.
8905 SW 87th Avenue, Suite 220
Miami, Florida 33176

Re: K052294

Trade/Device Name: Shoulder Nail Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation
appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: August 19, 2005
Received: August 30, 2005

Dear Mr. Hernandez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


Page 2 - Mr. Ernesto Hernandez

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: **Shoulder Nail Plate**

Indications for Use Statement

The **Shoulder Nail Plate** of the Shoulder Fixation System is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal Humerus.


(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ _____

OR

Over-The-Counter Use _____


(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K052294